IRB APPLICATION GUIDELINES
for
Submitting Protocols
to the
Institutional Review Board

The following Guidelines are provided to assist Principal Investigators (PI's) with their applications for Institutional Review Board (IRB) approval of research projects using Human Subjects. These Guidelines are intended to be helpful in explaining the concepts of protecting Human Subjects but may not be all inclusive. The official Policy and Procedures for the Protection of Human Subjects in Research and Research Related Activities is housed in the Office of the System Provost, Baker College. After a careful review of the Policy and Procedures and these Guidelines, any questions concerning these documents or any questions related to the application package should be addressed to the IRB Committee. Acknowledgement is herein given to the Office of Sponsored Programs at Florida Gulf Coast University for their assistance in preparing this document[1].

[1] Much of the manual has been adopted from materials supplied by Florida Gulf Coast University Office of Research and Sponsored Programs. The assistance of Donna Stremke is gratefully acknowledged.

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I. INTRODUCTION

This guide has been prepared for faculty, staff, students, and community members (from within or outside of Baker College) who are or will be involved with research projects that involve human subjects. It is designed to be a user-friendly guide to the Institutional Review Board's (IRB's) Policy concerning the Protection of Human Subjects. This guide provides step-by-step procedures for preparing and submitting applications to the IRB. For the regulations and ethical principles regarding research involving human subjects at Baker College, please refer to the IRB Policies.

The intent of the IRB policies and related review procedures is to safeguard the rights and welfare of human subjects (by the elimination or minimization of research-related risks and the requirement for informed and voluntary participation by subjects) and to ensure Baker College is in compliance with federal rules.

The goal of the Baker College Human Subject Institutional Review Board (IRB) is to work with investigators to promote research which protects all participants, including the College and its investigators. Failure to follow established policies and procedures, or to disregard ethical standards will result in the cancellation of the research project, and may result in additional consequences.

All faculty, staff, students and community members must complete the CITI Research Ethics and Compliance Training before submitting an application to the Baker College IRB. Currently, this training is available online at https://about.citiprogram.org/en/homepage/.

II. INVESTIGATOR ROLES

A. Students (Baker College)

Note: The following section provides information for Baker College System students and faculty members who supervise student research.

A1. Types of Student Research[2]

a. Undergraduate or Graduate Dissertation or Thesis Research and/or independent study research projects that involve interactions with human subjects.
    1. All undergraduate or graduate student dissertations, thesis and independent study research should follow the same procedures as those for faculty research described below.

[2]The authors wish to acknowledge that some wording in this section has been taken from http://www.scu.edu/SCU/Departments/SponProj/human_subject2.htm#student and modified to meet the needs of Baker College. (Shall we put this as a second note on the first page?)

2. The student's faculty sponsor is responsible for informing the student of the necessary procedures and assisting the student in complying with all applicable policies and procedures.

b. A class research project involving survey research with human subjects.
    1. Students wanting to collect data from human subjects as part of the requirements for a specific class may conduct opinion research that is not specific to the behaviors and/or experiences of the interviewees, as long as informants are not identifiable by name or description. Such research is not subject to review by the IRB.

c. Class assignments primarily intended for educational purposes that involve interaction with human subject(s) that are not intended to produce generalizable knowledge or intended to result in distribution of data or information beyond the classroom, but are primarily intended to demonstrate how research is conducted.
    1. Class-based research that can be categorized as demonstration projects, which are designed to demonstrate principles and procedures of research, but do not collect and maintain data for analysis purposes (beyond the classroom assignment) may be conducted without further oversight, provided that students have the option not to participate as a research subject.
    2. Faculty are encouraged, in such cases, to ensure that students have reviewed appropriate materials, including this handbook, so that they are prepared and knowledgeable for the independent conduct of research in the future.

d. Students who are utilizing data from a research project that already has IRB approval.
    1. When a student is working on a project that already has Human Subjects approval and that student will use some of the data to fulfill a course or degree requirement, such as a senior thesis or master's degree, the original principal investigator must submit an amendment to the HSC requesting the student be added as a researcher on his/her project for the stated purpose.

e. Students who are utilizing archival data sets.
    1. Students utilizing archival data sets are not considered to be interacting directly with human subjects, and no oversight need be provided by the IRB. If the archival data has been generated through past research or data collection at Baker College, it may be used only if its use only is consistent with the original protocol filed with the Institutional Review Board or after an updated protocol has been filed.

In the event that IRB review is not needed for a particular classroom research project, the student researcher and the instructor are not relieved of the obligation for the ethical use of human subjects. Consequently, the researchers should adhere to ethical standards and use informed consent when appropriate.

A2. Student Responsibilities

The student conducting research will comply with all guidelines established by the program and College, as well as any applicable guidelines established by any external organization involved in the project.

The student is responsible for understanding that participation by any person in a research project is voluntary. In the event that any compensation is to be provided, such compensation will be approved in advance by the Institutional Review Board to ensure that principles of "reasonableness" are maintained, and that participants are not subject to undue influence as a result of the compensation offered. Generally, compensation is limited to reasonable reimbursement for the participant's actual time.

The student is responsible for submitting for approval all research assignments, prior to his or her initiation. Submission must be made in accordance with established policies and procedures to either the individual faculty member or the IRB.

The student is responsible for obtaining approval of all research instruments developed in association with a research assignment, i.e., surveys, questionnaires, etc. Approval from the overseeing faculty member or the IRB must be obtained prior to the start of any data collection.

The student is responsible for considering the cost of completing an assignment. Projects should not be initiated that have the potential to become a financial burden to the student.

The student is responsible for all legal costs incurred in the conduct of the research, as well as any unanticipated costs that result because of the research or any individual's involvement in the research project.

B. Faculty and Staff (Baker College)

The faculty or staff member conducting research will comply with all guidelines established by the program and College, as well as any applicable guidelines established by any external organization involved in the project.

The faculty/staff member is responsible for understanding that participation by any person in a research project is voluntary. In the event that any compensation is to be provided, such compensation will be approved in advance by the Institutional Review Board to ensure that principles of "reasonableness" are maintained, and that participants are not subject to undue influence as a result of the compensation offered. Generally, compensation is limited to reasonable reimbursement for the participant's actual time.

The faculty/staff member is responsible for submitting for approval all research assignments, prior to their initiation. Submission must be made in accordance with established policies and procedures to the IRB board.

The faculty/staff member is responsible for obtaining approval of all research instruments developed in association with a research assignment, i.e., surveys, questionnaires. Approval from the IRB board must be obtained prior to the start of any data collection.
The faculty/staff member is responsible for considering the cost of completing an assignment. Projects should not be initiated that have the potential to become a financial burden to the member/college.
The faculty/staff member is responsible for all legal costs incurred in the conduct of the research, as well as any unanticipated costs that result because of the research or any individual's involvement in the research project.

C. Faculty, Students and Community Members (from other institutions)

Any faculty/students/community members conducting research will comply with all guidelines established by the program and College, as well as any applicable guidelines established by any external organization involved in the project.
The faculty/students/community member is responsible for understanding that participation by any person in a research project is voluntary. In the event that any compensation is to be provided, such compensation will be approved in advance by the Institutional Review Board to ensure that principles of "reasonableness" are maintained, and that participants are not subject to undue influence as a result of the compensation offered. Generally, compensation is limited to reasonable reimbursement for the participant's actual time.
The faculty/students/community member is responsible for submitting for approval all research assignments, prior to their initiation. Submission must be made in accordance with established policies and procedures to the IRB board.
The faculty/students/community member is responsible for obtaining approval of all research instruments developed in association with a research assignment, i.e., surveys, questionnaires. Approval from the IRB board must be obtained prior to the start of any data collection.
The faculty/students/community member is responsible for considering the cost of completing an assignment. Projects should not be initiated that have the potential to become a financial burden to the member/college.
The faculty/students/community members are responsible for all legal costs incurred in the conduct of the research, as well as any unanticipated costs that result because of the research or any individual's involvement in the research project.

You must follow your own institution's IRB policies and procedures. In addition, you must adhere to Baker College's IRB policies and procedures outlined in the IRB website and in this document (including Section II-A and II-B).

III. BACKGROUND INFORMATION YOU NEED TO KNOW

A. DEFINITIONS

Human Subjects Research is a systematic investigation designed to develop or contribute to general knowledge, which involves the collection of data from or about living human beings.

Activities which meet this definition constitute "research," whether or not they are supported or funded under a program that is considered research for other purposes. For example, some "demonstration" and "service" programs may include research activities. Human Subject Research does not include research utilizing published or publicly available documents or research on elected or appointed public officials or candidates for public office.

Human Subject means a living individual from whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.

IRB refers to the human subjects Institutional Review Board. This board is appointed to review research involving human subjects for compliance with applicable federal, state, and local regulations. The IRB membership includes Baker College faculty and staff from relevant disciplines, as well as member(s) of the local community.

At Risk means to be placed in a position with greater potential for physical, mental, social, or financial harm than would be expected for that individual in his or her normal occupation or daily activities.

Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Reasonable Risks means the relationship of anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result.

B. IRB SCOPE

All research involving human subjects, including research training, must be reviewed and approved by the College's Institutional Review Board (IRB) before any human subject research can begin. The IRB has full authority to approve, require modifications, or disapprove all research activities that fall within its jurisdiction.

There are three types of review classifications--Exempt from Further Review, Expedited Review, and Full Board Review. Criteria for qualifying for a particular review category are specified by the Department of Health and Human Services. The Exempt classification does **not** mean that the research project is exempt from review by the IRB; rather, it is a classification assigned by the IRB after its review of the protocol to indicate that the project is exempt from further IRB review as long as there are no modifications in the procedures. **Submission of an application is required even if the PI thinks the project should qualify as Exempt.**

A detailed discussion of the criteria for the classifications is found in Appendix A. This information is included for your general knowledge and to help you determine a general time frame for the review process.

C. EXPLANATION OF APPLICATION ELEMENTS

The IRB review process focuses on the consideration of the following elements:

- **Risk**. Are the procedures and subject's participation adequately described? Do the study's procedures place the subject at risk in any form? Are risks fully described? Is the risk minimal or reasonable as defined by the Policy? Are the procedures adequate to minimize any risk?
- **Benefit**. If there are potential risks, should the knowledge from the research be pursued? Do the benefits outweigh the risks? Have the benefits to the subject and/or society been described?
- **Informed Consent**. Are the subjects provided with sufficient detail in the consent form to assure voluntary and informed consent? Are participants notified that they can withdraw at any time? Are the participants informed about their recourse in the event of injury? Are the participants provided with a name and phone number of a person to call with any questions or problems? Is there any indication of coercion or undue influence?
- **Confidentiality/anonymity**. Is the selection of participants/subjects fully explained? If the subjects are anonymous, how is anonymity ensured? Are the procedures sufficient to allow for confidentiality of information about individual subjects in both gathering and dissemination of information? Are security measures adequately described?
- **Special or vulnerable populations**. Are vulnerable populations involved? If so, have particular and appropriate steps been taken to assure they or their legal guardians understand what is going to happen, their participation is voluntary, legal consent has been obtained, etc.? Is selection of subjects equitable?

A pivotal issue in the review process is deciding whether or not the proposed research might place subjects at more than minimal risk. There is no simple, objective criterion that can be applied in all such judgments. The College's policy document on human subjects' research states that "minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological tests or examinations." This definition acknowledges that most people's daily lives include challenges and stresses. In practice, the kinds of experiences that "most people" have on a "typical" day are considered minimal risk, exposing subjects to the kinds of physical or psychological stressors that make some of our days rather painful or disturbing would be judged to involve more than minimal risk, despite the fact that such experiences may not always cause lasting harm.

Two other issues central to the evaluation of virtually all proposals are the issues of **confidentiality** and **informed consent**. Your application must provide a thorough description of the steps that will be taken to maintain the confidentiality of data. For instance, if the participants will be completing written questionnaires, will they be asked to include or omit their names from these forms? Even when names are omitted, individuals can sometimes be identified from demographic or other background information that they provide. When

identifying information is needed, what other steps will you take to ensure that the data will remain confidential? What steps will you take to ensure the confidentiality of photographs and video or audio recordings? **A statement to the effect that "confidentiality will be maintained" is not sufficient.**

You must obtain the legally effective informed consent of your participants or of their legally authorized representatives. This will mean obtaining a signed consent in most cases. Informed consent must be written or explained in language that is understood easily by the subject or representative, usually language appropriate for the 7th or 8th grade reading levels. You must seek such consent under circumstances that provide the prospective subject with sufficient opportunity to consider whether or not to participate. These circumstances must also minimize the possibility of coercion or undue influence. Subjects must be informed of any foreseeable risks or discomforts. They must also be given an explicit statement explaining that their participation is voluntary, that refusal to participate will involve no penalty, and that they may discontinue participation at any time without penalty.

In the case of an anonymous questionnaire in which a signed informed consent form would provide the only means of identifying the subject, an explanatory letter (see the sample in the "Sample Informed Consent Forms" under the IRB Website) attached to the questionnaire may substitute for a signed informed consent form.

IV. THE APPLICATION

The application is to be completed by the principal investigator (PI). If the principal investigator is a student, the application must be approved by the student's faculty sponsor. The responsibility for complying with the Policy and Procedures is shared by the faculty sponsor and the student.

A. Authorization and approval at External Data Collection Sites

In many cases, PI's will become involved in research projects that reach out to community partners or into business and industry. In all cases, approval must be obtained in writing from all agencies or organizations involved in the research in a scanned format.

Approval by the Baker College system and/or the Baker College Institutional Review Board authorizes a PI to proceed with a particular project but does not authorize the PI to proceed at a location outside of Baker College.

Prior to collecting data at any off-campus site, the PI's must receive permission in writing to operate at a specific site (Note: Students must return this permission to the faculty member overseeing the research project). In some cases, this may require the PI's to submit an application to the Institutional Review Board operating within the desired research setting in addition to an application to the Baker College Institutional Review Board. This is particularly likely to occur in medical or hospital settings where permanent IRBs are generally in place. The

only exception to this will be the collection of observational data of public behavior in public settings that does not involve direct contact between the researcher and the research participant and does not involve the collection of any information that would allow the individual research participant to be identified. Such research does, however, still require the approval of the Baker College Institutional Review Board.

B. Authorization and approval within Baker College

Baker College faculty, students and staff must obtain approval and signature from the administrator of the campus where they work or study prior to submitting the IRB form (see the IRB Application Package).

In addition, if the PI's plans to use Baker College students or staff as subjects at any Baker College campus, they must obtain approval and signature from the administrator of the campus where the research is being conducted prior to submitting the IRB form (see the Baker College Research Request Form).

C. The Application Submission

The PI submits a complete IRB Application form (Google form) for signatures.

All links to the Google Forms for IRB submission are located on the IRB Website.

In addition, there are process workflows for each type of IRB application located on the IRB Website.

Note: Researchers or IRB Applicants from outside Baker College should contact the IRB Chairperson for further information and direction.
IRB Chairperson: Tomeika Williams / twilli176@baker.edu

Any questions about the completion of the application should be directed to the Chair of the IRB.

Please bear in mind that you may NOT initiate any research involving human subjects until you have received written notification of IRB approval.

If you have submitted this project to an external agency for funding, attach one copy of the external proposal to the application. If you intend to submit this project to an external agency for funding, forward a copy of the external support proposal to the Chair of the IRB as soon as feasible.

V. THE REVIEW PROCESS

Once the Google Form IRB Application is signed by the Principal Investigator the application is automatically logged into the system.

On a weekly schedule, the IRB chair will conduct a Review to determine completeness of the application package and determine the type of review (exempt, expedited, or full board review) appropriate to the project application.

The Chair will notify you of the results of the Review and the type of review required for your application. If your package is missing any required components, your application will be returned to you with instructions on how to complete it. You may correct any deficiencies and return the package for a second review. If your application is deemed eligible and ready for an Expedited Review, you will be invited (but not required) to attend the Review. If the Chair determines the application needs a full board review, you will be asked to provide additional copies.

The Expedited Committee may request clarifications or changes. A detailed, written explanation of the Committee's concerns and requests will be forwarded to you within two weeks of the Committee's review.

If your application does need modifications, three copies of all modified sections or attachments are to be submitted to the Chair of the IRB, with the modifications highlighted or marked so that the Expedited Committee can quickly locate them. Do **not** put the modifications in the form of assurances that they have been made (i.e., a letter or memo assuring that the modifications have been or will be put in place). The **complete** modified application must be on file with the Chair of the IRB.

Written notification of the Committee's approval of your application (or a request for further clarifications, if needed) will be forwarded to you within two weeks of the Committee's review of your modified application.

If your application is to appear before the Full Board for review, you will be asked to provide additional copies and you will be invited to attend the review. A Full Board Review may request modifications or clarifications; these will be forwarded to you in writing within two weeks of the Board's review. You will receive written notice of approval or denial of your application.

APPENDIX A: REVIEW AND APPROVAL CATEGORIES

It is the policy of Baker College that the IRB will utilize Department of Health and Human Services criteria for all projects involving human subjects in research when evaluating proposed research protocols. The chairperson or one or more IRB members designated by the chairperson may determine one of three actions: Exemption from Further Review, Expedited Review, or Full Board Review. Please note that any research project may fall under only one category. The following section elaborates upon the types of IRB reviews.

I. Research Considered Under the "Exempt From Further Review" Category

In order to establish an individual research project as Exempt from Further Review, the principal investigator must complete the "Application for Approval of Investigations Involving the Use of Human Subjects". Final determination as to whether a research project is Exempt from Further Review rests with the Chair of the IRB or his/her designee. If the project is certified Exempt from Further Review by the IRB, the principal investigator need not resubmit the project for continuing IRB review as long as there are no modifications in the exempted procedures. **Submission of an application is required even if the PI thinks the project should qualify as Exempt.**

The following categories are considered Exempt from Further Review:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices such as research on regular and special educational instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement) if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

3. Research involving survey or interview procedures, *EXCEPT* where all of the following conditions exist:

    a. responses are recorded in such a manner that the human subject can be identified, directly or through identifiers linked to the subject;
    b. the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability; and
    c. the research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

4. Research involving the observation (including observation by participants) of public behavior *EXCEPT* where **any** of the following conditions exists:

    a. observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subject;
    b. the observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability; and
    c. the research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

5. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

6. All research involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.

II. Research Considered Under the "Expedited Review" Category

The principal investigator shall submit the "Application for Approval of Investigations Involving Use of Human Subjects". Research activities involving no more than "minimal risk" to subjects and in which the only involvement of human subjects will be in one or more of the following categories may be reviewed by the IRB Expedited Review Subcommittee:

1. Collection (in a nondisfiguring manner) of hair, nail clippings, deciduous teeth, and permanent teeth if patient care indicates a need for extraction.

2. Collection for analysis of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

3. Recording of data from subjects 18 years of age or older using non-invasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also include such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, and thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays and microwaves).

4. Collection of blood samples by fingerstick or venipuncture, in amounts not exceeding 450 milliliters in an eight-week period, and no more often than two times per week, from subjects 18 years of age or older who are in good health and not pregnant.

5. Voice recordings made for research purposes such as investigations of speech defects.

6. Moderate exercise by healthy volunteers.

7. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

8. Research on individual or group behavior or characteristics of individuals such as studies of perception, cognition, game theory, or test development, in which the investigation does not manipulate subject's behavior, and the research will not involve stress to subjects.

9. Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth, and the process is accomplished in accordance with accepted prophylactic techniques.

III. Research Considered Under the "Full Board Review" Category

Any research or training project involving the use of human subjects which does not fall into the "Exempt from Review" or the "Expedited Review" categories must be submitted to the IRB for a full board evaluation. The principal investigator must complete and submit the "Application for Approval of Investigations Involving the Use of Human Subjects".

IV. Conditions under Which IRB Approval is not required for Survey Research

Students wanting to collect data from human subjects as part of the requirements **for a specific class** may conduct **opinion research** that is not specific to the behaviors and/or experiences of the interviewees, as long as informants are not identifiable by name or description.

For example, IRB approval is **not required** for a student to survey people's opinions about topics such as the following:

a. opinions of political candidates or issues
b. opinions regarding American-made vs. foreign-made products
c. opinions concerning environmental issues or policies
d. opinions regarding the subject's favorite television show, preferred vacation spot, musical preference, etc.

The key factor shared by these examples is that they do not require subjects to reveal anything about their personal experiences, behaviors, and/or identity. Therefore, the subjects are not considered to be placed **at risk** by their participation. Thus, in these cases, IRB approval is not

required. Additional information concerning student research, and how it is handled by the IRB, can be found in the Student Research Manual.

APPENDIX B: FREQUENTLY ASKED QUESTIONS

1. What types of projects must faculty submit to the IRB?

   The human subjects review process applies to all research involving the use of human subjects. This applies to research that is funded or unfunded; research that is undertaken by faculty, staff or students at Baker College; research done on the property of or using the facilities of Baker College; and/or research using College personnel or students as subjects.

2. What types of course activities do not require IRB approval, and can I make that decision?

   Course activities which use human subjects are exempt from review as long as the purpose is purely pedagogical and the results are intended solely for use within the classroom setting. One way to understand these criteria is to consider the purpose of the project. Classroom activities designed to teach research processes that do not involve collecting data for the purpose of creating knowledge are generally exempt. If the results have the potential for public dissemination, IRB approval must be obtained. Anonymous classroom assessment techniques of students for the purpose of improving classroom instruction would be considered exempt from IRB review. If the activities clearly fall within these criteria, the instructor/investigator could make this determination. If the instructor/investigator is not clear on the status of the project or would prefer that the IRB decide such status of the project, the instructor/investigator can submit the proposal to the IRB for review.

3. Do students undertaking a project as part of a class assignment require IRB approval?

   Certain types of survey research, conducted as a portion of a specific course, do not require IRB approval. This includes research in which the responses of participants are not identifiable by name or description, AND where the survey is seeking opinions about various topics. In cases where the participant is not asked to reveal personal experiences or behaviors, IRB approval is not necessary.

When survey research is conducted as a portion of a class in which a participant is asked to disclose identifying information, IRB approval is required. Further, survey research that seeks to identify participants only within a specialized population or investigates a variety of sensitive areas (available in the Baker College Rights and Welfare on Human Subjects Research Policies and Procedures) requires approval.

For all student research conducted as a part of a course, the protocol must be reviewed and approved by the course instructor, program head, and campus administrator.

All other research conducted with human subjects as part of a course will require normal IRB approval.

4. My project involves a community partner. Do I need Baker College IRB approval?

   Partnering with a community member in no way alters the Baker College employee's responsibility to participate in the IRB review process. All policies regarding the review and safeguards for research participants must be maintained in accordance with standard policy.

   In some cases, a community partner may have its own institutional review board. In these cases, the community partner may require adherence to policies that are more protective of a participant's rights than Baker College policy, and Baker College employees would be expected to comply with those policies. If an outside review board sets policy that is less stringent than Baker College policy, all employees will be required to adhere to the policy of Baker College.

   In either case, an application must be filed with the Baker College IRB.

5. Who determines that a project is exempt?

   Final determination as to whether a research project is exempt from IRB review is determined during the Review process following initial submission.

6. What happens if my IRB application is not approved?

   You are not authorized to start your project, but you may reapply with recommended changes.

7. What happens if I do not agree with the committee?

If you believe that the recommended changes indicate that there is a portion of the research that was not fully understood by the IRB, then you may choose to alter that part of the IRB application that appears to have been misunderstood, and resubmit the entire application for a full board review. It is recommended that in such cases the principal investigator attend the full board review to provide any clarification. If the application is again denied, it will be reviewed only following completion of all recommended changes.

8. I have a sponsored project for an outside organization that must be done within a tight time constraint. Do I need approval, and if so, how long will it take? Will review force me to reject the funding?

   Sponsored projects are treated as any other research projects. How long it takes depends on which level of review is required. Reviews are conducted frequently. The normal review process on a complete application may take three to six weeks; modifications to the application will extend this process.

   External funding of a project in no way alters the approval process. If the project is not approved by the IRB, the principal investigator may not begin work on the project. This may result in a loss of funds.

9. I submitted a protocol for review because it was part of an externally-sponsored project. The external sponsor did not fund my project. What do I do?

   Many agencies provide investigators with feedback about grant applications that are not funded. If you incorporate any of the suggested modifications into your research protocol, it will be necessary to obtain IRB approval on the new research protocol. Obviously, re-approval would be necessary with any change in the subject informed consent form.

   If you decide not to conduct the research, you should inform the IRB in writing and the IRB file will be closed.

10. I intend to use a standardized intelligence test (attitudinal or aptitude tests) in class for research purposes; do I need approval?

    A protocol would need to be submitted to the IRB for Review.

11. My potential subjects do not speak English in the home; how do I ensure they understand informed consent?

    To obtain Informed Consent for a non-English speaker to participate in research, the subject should be asked in his or her own language for consent/assent to participate.

Informed Consent form should be written in the subject's home language. OR Consent of a guardian who speaks the subject's language and understands the subject's linguistic culture is needed for any non-English speaker because the subject is not capable of giving fully informed consent. Assent of a non-

English speaker who is minor may be obtained verbally however, if assent of the subject is to be obtained verbally, the submission should include a description of how the investigator will ask for assent from the minor subject.

APPENDIX C: GUIDELINES FOR PARENTAL CONSENT

Research concerned with sensitive issues and involving the participation of minors is becoming more common. In most municipalities, individuals under the age of 18 are generally considered minors. Such research often presents difficult questions related to the protection of human subjects. The purpose of these guidelines is to help researchers plan procedures and prepare proposals that can be approved by the Behavioral IRB.

RISKS

Research on health and social issues often involves requesting sensitive information from subjects, some of whom may be minors. The procedures for collecting and handling such data often do pose risks to the subjects. These risks may include some or all of the following:

1. **Violation of Privacy:** Collection of data concerning at-risk or socially questionable behavior (for example, questions about substance use or sexual activity) are viewed by many individuals as violations of privacy.

2. **Legal Risks:** Data concerning illegal behaviors may place individuals at risk of legal action, if (a) names can be linked to particular responses or observations and (b) the research has not received specific legal protection (e.g., by Certificate of Confidentiality).

3. **Psychosocial Stress and Related Risks:** Procedures that raise sensitive issues may generate stress for participants. For example, questions about at-risk behaviors may cause individuals to feel stress related to their self-images or contribute to perceived peer pressure.

4. **Social Relations:** Because relevant questions often request information about the behavior or relations with family members, peers, or authorities, some procedures may pose a risk to those relations if confidentiality is not adequately safeguarded.

In addition to these risks, which may be applicable to either minor or adult subjects, research involving minor subjects may also pose risks to parents or other family members. In particular,

research soliciting information about at-risk behaviors of family members may place those individuals at legal risk. Furthermore, some parents may believe that their right to determine the activities of their children is violated if signed parental consent is not obtained.

PROTECTION

In general, protection from these risks may be achieved by (a) ensuring the confidentiality of information obtained about subjects, (b) providing access to or information about resources for coping with psychosocial stress caused by the research procedures, and (c) ensuring that the procedures meet the principles of voluntary participation and informed consent. Guidelines for achieving this protection include:

1. **Confidentiality and Anonymity:** Information is considered **confidential** when only the investigator has access to the identity of the individual about whom information is obtained. Information obtained from individual subjects must be kept confidential from public scrutiny, from parents and peers, and from legal and school authorities. This is most easily accomplished by collecting data in a manner that insures **anonymity**. Information is considered **anonymous** when names or other identifying information about individual subjects can at no point be associated with observations or with responses to a survey or other data collection instruments. However, anonymity is not always compatible with research goals (for example, when data collected from the same individual at different times must be linked for analysis). In these cases, procedures for protecting confidentiality must be fully spelled out. When information that might put subjects at legal risk is to be collected, it is the investigator's responsibility to obtain and document specific legal protection (e.g., by Certificate of Confidentiality obtained from a governmental agency).

2. **Psychosocial Stress:** The procedures needed to help subjects cope with psychosocial stress that may arise from participating in research will vary depending on the exact nature of the research. If such procedures are required, it will typically be sufficient to provide subjects with information about resources (e.g., counselors) available to them. In cases in which more severe stress seems likely, it may be necessary to ensure that someone qualified to handle such stress be present during data collection.

3. **Voluntary Participation and Informed Consent:** These are basic ethical principles for conducting research with human subjects. Subjects **must** be informed that participation is voluntary, answers to specific questions may be withheld without penalty, and they may withdraw from the research at any time. Because research of this type is often conducted in an institutional setting where subjects' presence is mandatory (e.g., the school classroom), it is especially important that procedures for meeting this requirement be made explicit in the proposal.

The procedure for obtaining informed consent must be documented; often this requirement can be met by informing subjects that responding to survey items

constitutes permission to use the collected data, without identifying individual subjects, in published reports of the research.

PARENTAL CONSENT

A particular concern with research of this nature is the role of parental consent for the participation of minor subjects. The general requirement is that explicit parental consent be obtained in writing for each subject. However, there are situations in which such a consent procedure is not appropriate. The IRB **may** approve the research as meeting federal requirements for exemption when **all** of the following conditions are met:

1. Data collection is **anonymous**; that is, at no point are subjects' names associated with information about them.

2. Data are collected as part of a required or elective education program in which subjects are already participating; for example, a school curriculum, school band, school sports, etc.

3. Participating in the research does not involve risks greater than those incurred by participating in the relevant educational program.

These conditions are not met, and parental consent **is** required, when:

1. A data base linking identifying information with responses is maintained, or subjects' identities can be otherwise linked to information about them; or

2. The research instruments elicit information about the behavior of specific individuals, rather than about conceptual knowledge covered by the educational program.

There may be additional exceptions to this requirement in other special circumstances. Such circumstances must meet criteria established by 45 CFR 46 at sections 116.d. and 408.c. Usually such exceptions are based on demonstrating one or more of the following:

1. That seeking parental consent increases the risk to subjects;

2. That no meaningful parental consent can be obtained; or

3. That the research cannot practically be conducted if parental consent is required (please note that "practically" here refers to insurmountable obstacles rather than the researcher's convenience).

Researchers are reminded the reading level of informed consent documents should be appropriate to the typical educational background of the research population, and documents designed for college students may not be suitable for seeking parental consent. Researchers

should write these documents using short sentences and everyday language. For example, "voluntary participation" may be paraphrased by "you do not have to do this if you don't want to."

APPENDIX D: OBTAINING AND DOCUMENTING ASSENT FROM MINORS

Parental consent is usually a prerequisite to the recruitment of human research subjects who are minors. However, parental consent constitutes only half of the consent process. Assent, the agreement of a minor to participate in research, is the second component of the informed consent procedure for minors.

The means of obtaining assent from minors must be appropriate for the age ranges and levels of mental development found within the proposed subject pool. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research expects that assent be requested from children who are 7 years of age or older. However, for children between the ages of 7 and 18, the appropriate method for obtaining assent will vary.

Age 6-7	A simple oral description of the child's involvement is given to the subject and oral assent is requested. The procedure may be documented on the informed consent form by the presence of the signature of a witness.
Age 8-13	A more complete oral description of the research (in layman's terminology) is given to the subject. Verbal assent is requested. The procedure may be documented on the informed consent form by the signature of a witness.
Above age 13	Written assent should be requested from both parent and child, using age-appropriate and background-appropriate documents.

Although age is used as the primary criteria in determining an appropriate means of obtaining assent, factors such as literacy and mental development must also be considered. The need for flexibility in the methods for obtaining assent from minors is universally recognized. Because a single method of obtaining assent may not be appropriate for all potential subjects, investigators may need to be prepared to use different approaches with different subjects. As in any consent process, the primary concern is the subject is able to understand the explanation that is presented. The need for a witness to document verbal assent procedures is dependent upon the complexity of the research and the risks to the subject. Minor status may be defined differently by federal government agencies.

APPENDIX E: GUIDELINES FOR INTERNATIONAL RESEARCH INVOLVING HUMAN PARTICIPANTS

These guidelines are prepared as a brief overview of things to consider when conducting research in international settings. The Institutional Review Board (IRB) believes that culturally appropriate procedures are an important aspect of protecting participants in research. Because there are specific rules to be followed when conducting research involving human participants in countries other than in the United States, there are often local customs that are not usually considered in the IRB deliberations. These differences must be brought to the attention of the researcher. The guidelines contained in this document are intended to apprise researchers of the various issues that arise when conducting research with human participants in international settings.

1. When documents are translated into a language other than English, the researcher should provide a copy of the document in English, a copy in the language to be used in the document, and a letter from an individual (e.g., a Baker College faculty member) indicating that the translated version of the document is complete and does not contain information that is not presented within the context of the English version of the document.

2. When human participants under the age of 18 are to be used in research, written parental permission is required. If local customs and regulations are such that active parental permission would be culturally inappropriate, the researcher must supply the IRB with proof that such permission is not culturally appropriate. Examples of such proof would be specific regulations (in English and certified to be accurate) that indicate that such permission is not required, an official letter from a ranking official in the country of interest indicating that such permission is not culturally appropriate, or being accompanied to the IRB meeting by another Baker College employee (preferably a faculty member) who can attest to the cultural inappropriateness of the requirement for active parental permission. In those cases where seeking active parental permission for minors to participate in research is culturally inappropriate, a waiver of such permission may be granted at the discretion of the IRB, as long as the research does not place the participant(s) at untoward risk. Regardless, the participant(s) in the research retain(s) the right to discontinue participation, without penalty, at any time during the gathering of data.

3. If a waiver of active parental permission is granted, a letter informing the parents of the research, written at a literacy level that would be understood by the parents, must be prepared and sent to the parents by the most expeditious method possible.

4. Letter(s) of agreement from the appropriate official(s) (e.g., government officials, school officials, community officials, Chief Executive Officers, etc.) indicating that the research protocol and any and all instruments to be used (including any biomedical equipment) have been reviewed and are acceptable to those officials are to be submitted. The certification letter must be on letterhead stationery and carry an original signature.

5. When appearing before the IRB to answer questions about the research, it is helpful if an individual who is familiar with the culture (unless the researcher is recognized as an "expert") can accompany the researcher.

6. If data will be collected by someone other than the researcher, that individual or individuals must be identified and letters of agreement presented to the IRB. If the data collector(s) will have access to the data, such access must be specified.

7. Specific processes for assuring anonymity and/or confidentiality of all data must be specified, particularly if the analysis will occur away from Baker College.

8. Processes for transporting data from the international location to Baker College, with particular reference to #6 above, must be specified.